EC Declaration of Conformity

Company	**GENOMICA, S.A.U.** Parque Empresarial Alvento Edificio B Calle Vía de los Poblados, 1 - 1ª planta 28033 Madrid
Product:	**AUTOCLART PLUS** (Clinical Array Technology). IVD laboratory instrument
References:	ACP
Classification:	Class A. Rule 5. Annex VII.
Conformity assessment route:	Annex III of Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

Genomica, S.A.U, declares under its sole responsibility that the diagnostic device AUTOCLART PLUS (Clinical Array Technology) conforms to the relevant provisions of the Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

Standards applied	EN ISO 9001:2008, EN ISO 13485:2016. EN ISO 14971:2012. EN 15223-1:2016, EN 13612:2002. EN ISO 18113-3:2011, EN 62304:2006. EN 61010-2-101:2002. EN 61326-2-6:2006
Notified Body	NA
EC Certificate	NA
Period of validity:	NA

uthorised Signatory

Name:	Dra. Rosario Cospedal
Position:	Managing Director
Date	Madrid, 22nd November 2017